Positron Emission Tomography (PET) Services
Review Criteria

(Final Draft as of 9/05/03)

DEFINITIONS

Positron Emission Tomography The Center for Medicare and Medicaid Services defines PET as a noninvasive diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the human body. A PET scanner means diagnostic equipment that uses a positron camera (tomograph) to produce cross-sectional tomographic images. The images are obtained from positron emitting radioactive tracer substances (radiopharmaceuticals) such as 2-(F-18) Fluoro-D-Glocose (FDG) which are administered intravenously to the patient. The radioactive tracers may be produced on-site, e.g. with a cyclotron, or may be ordered from commercial distributors. As a result, factors such as equipment cost, geographic distribution/availability of distributors, and other related factors (regulatory compliance/certification) shall be considered by the Agency in its review of all PET applications.

PET differs from other nuclear medicine modalities in the type of radiation emitted and in the type of scanner required to detect it. By measuring the distributions of certain radiotracers in the body some time after they have been administered, PET can be used to diagnose physical abnormalities and to study body functions in normal subjects.

PET scanners compliment the information obtained from CT and MRI equipment that are used to depict form (tissues and bones). First developed in the 1970s, initial PET scanners were dedicated machines performing only that service. PET scanners can be either fixed/stationary or mobile. Current technological adaptations include hybrid machines, such as combined PET-CT (computed tomography) scanners that are capable of performing a variety of nuclear medicine studies. *Note: for purposes of this definition, any hybrid machine that is primarily used for non-PET applications or whose use results in a level of 90% or less as PET-only applications shall be referred to as a non-dedicated PET scanner.*

Mobile PET Scanner means a PET scanner and transporting equipment that is moved to provide services at two or more host facilities, including facilities located in adjoining or contiguous states of the Continental United States.

PET Service Area refers to a defined primary and secondary service area and means a geographical area, usually multiple Tennessee counties in an area consistent with Tennessee's Health Department Regions or multiple Tennessee counties and areas of other states, with sufficient population and medical services including, but not limited to, existing oncology and cardiology diagnostic and treatment services. Preference will be given to those applicants who document the availability of actively practicing physician specialists, including medical oncologists, cardiologists, and neurologists, and who provide documentation of a sufficient number of patient referrals, by clinical diagnosis, to meet the minimum standards for stationary and mobile PET units. The PET service physician medical director shall be an active member of a local area hospital medical staff. A fully operational program (a PET program that operates at least eight (8) hours a day, five (5) days a week) should be located at a site which would allow accessibility for approximately 75% of the service area's population.

PET Procedure: A PET diagnostic scan or combination of scans performed on a single patient in a single session. This unit of measure is directly related to and verified by the provider's common procedure terminology code (CPT code) utilized to document the patient session.

Capacity: Stationary Units: The measure of the optimal number of PET scans per PET unit per year based upon the type of PET equipment to be used (e.g., dedicated, hybrid, stationary, mobile). The optimal efficiency or capacity for a stationary, fully-dedicated PET scanner is 1,250 procedures/year. Total capacity of a PET scanner is 1,560 procedures per year and is based upon a daily operating efficiency of six (6) procedures/day times 260 days of operation per year. Note: the total capacity measure of dedicated PET units is expected to increase as a result of advances in equipment technology and improvements in provider operating efficiencies.

Mobile Units: The optimal capacity of a fully-dedicated mobile PET unit at a single host site is 720 procedures per year or 80% of total capacity. Total capacity of a mobile PET scanner is 900 procedures/year and is based upon a daily operating efficiency of at least 6 procedures/day times three (3) days per week or approximately 150 days of operation per year.

Service Area Capacity: The estimate of the number of dedicated PET or hybrid PET units needed in a given service area. The estimate is based upon an optimal capacity of 1250 procedures/year for a stationary PET unit and the quantitative estimate of the number of patients who potentially could benefit from PET diagnostic services, especially those patients pertaining to the following categories:

those patients where the use of PET services is essential to the diagnosis, treatment or surveillance of cancer, including, but not limited to, melanoma, colorectal cancer, lung cancer and lymphoma; and
those patients who are either non-emergent candidates for open heart surgery or therapeutic cardiac catheterization procedures ; and
those patients with a diagnosis of partial complex epilepsy for whom surgical intervention is being considered; and
any other patient population that may benefit from the accessibility to stationary or mobile PET services as a result of expanded clinical applications and changes in the reimbursement of PET services by third party payors, including those pertaining to programs administered by the Center for Medicare and Medicaid Services.

In addition to the above determinants of service area capacity, applicants shall consider demographic patterns, including the results of estimates of population health risk factors and population-based cancer, heart disease, or other applicable clinical incidence rates. Applicants shall also document the extent, if any, of diagnostic oncology, cardiac and neurological medical services in the proposed service area in its determination of the need for PET services.

STANDARDS

1. The applicant shall demonstrate that the proposed service area has a population and a medical community sufficient to utilize a positron emission tomography (PET) stationary unit at an optimal rate of at least 1,250 procedures per year or that amount equal to 80 percent of the total capacity of a dedicated and stationary PET unit as determined by the Health Services and Development Agency during its most recent review.

2. Applicants proposing new stationary unit PET services must project a minimum of at least 900 PET procedures/year (6 procedures/day times 150 days) in the first year of service, 1,250 procedures in the second year (80% of total capacity/year), and 1,560 procedures (total capacity at peak operating efficiency) in the third year of operation and annually thereafter. Providers proposing a mobile PET service would not be subject to this requirement if fewer than 150 days of service per year are provided at a given location. The projection of need for the PET service, whether by statio nary or mobile unit, must include demographic patterns, including analysis of applicable population-based health status factors, estimated utilization by patient clinical diagnoses category (ICD-9), and documentation demonstrating that the applicant is providing or has referral arrangements with other medical providers that offer comprehensive cancer and cardiac diagnostic and treatment services.

All providers applying for a proposed new PET service should provide documentation that supports that the proposed location is accessible to approximately 75% of the service area's population.

All providers shall document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost and quality of care.

Any provider proposing new mobile PET services must demonstrate that it offers or contracts with providers that offer, as a minimum, cancer treatment services, including radiation, medical and surgical oncology services.

3. A need exists for one additional stationary, dedicated PET unit in a service area when the combined average utilization of existing PET service providers is at or above 80% of the total capacity of 1,560 procedures during the most recent twelve-month period reflected in the Joint Annual Report maintained by the Tennessee Department of Health or the provider medical equipment report maintained by the Tennessee Health Services and Development Agency. The total capacity per PET unit is based upon the following formula:

Stationary Units: Six (6) procedures/day x five (5) days/week
equals 1,560 procedures/year
Mobile Units: Six (6) procedures/day ***x*** three (3) days/week
equals 900 procedures/year

The provider shall demonstrate that its acquisition of an additional stationary or mobile PET unit in the service area has the means to perform at least 900 PET procedures or 300 mobile PET

procedures, respectively, in the first full one-year period of service operations in accordance with the standard specified in # 2 above. The provider shall also demonstrate the degree to which it either offered or contracted with cancer and heart disease diagnostic and treatment services for patients in the service area.

The applicant must provide evidence that the PET equipment is safe and effective for its proposed use.

The United States Food and Drug Administration (FDA) shall certify the proposed equipment for clinical use.

The applicant must demonstrate that the proposed PET service will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

The applicant must demonstrate how emergencies within the PET facility will be managed in conformity with accepted medical practice.

The applicant must establish protocols that assure that all clinical PET procedures performed are medically necessary and will not unnecessarily duplicate other services.

e. The PET service must be under the medical direction of a licensed physician. The applicant shall provide documentation that attests to the nature and scope of the duties and responsibilities of the physician medical director. Clinical supervision and interpretation services must be provided by physicians who are licensed to practice medicine in the state of Tennessee and are board certified in Nuclear Medicine or Diagnostic Radiology. Licensure for the handling of medical isotopes and radiopharmaceuticals by the Nuclear Regulatory Commission is required. Those qualified physicians that provide interpretation services must have additional documented experience and training in PET technology. Cardiac applications of PET scanning may be interpreted by licensed physicians who have experience, training, credentialing and licensure in Cardiac Nuclear Cardiology.

f. All applicants must seek and document emergency transfer agreements with local area hospitals, as appropriate. Applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

5. An exception to the standard number of procedures may be considered by the Health Services and Development Agency in accordance with the needs of health policy or mandate pertaining to medically underserved geographical areas, specifically with respect to the documented prevalence of cancer, heart disease , neurological impairment or other clinical conditions applicable to PET services. The applicant must fully document that the proposed PET service offers a unique and necessary opportunity to favorably contribute to the improved health status of residents in the proposed service area.